

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS**

**IN RE: TESTOSTERONE REPLACEMENT
THERAPY PRODUCTS LIABILITY
LITIGATION**

**Case No. 1:14-CV-01748
MDL 2545**

JUDGE MATTHEW F. KENNELLY

THIS DOCUMENT APPLIES TO ALL CASES

**MASTER ANSWER OF DEFENDANT BESINS HEALTHCARE, S.A. TO PLAINTIFFS'
FOURTH AMENDED MASTER LONG-FORM COMPLAINT AND JURY DEMAND**

Defendant Besins Healthcare, S.A. ("Besins S.A."), by and through its attorneys, hereby provides this Master Answer to Plaintiffs' Fourth Amended Master Long-Form Complaint (the "Master Complaint" or "Complaint"), and states as follows:

**ANSWER TO ALLEGATIONS REGARDING THE
NATURE OF THIS MASTER COMPLAINT**

1. Besins S.A. admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in Case Management Order (CMO) 20 entered in the pending MDL relating to testosterone replacement therapy products ("TRTs"). The Master Complaint, being in writing, speaks for itself and any remaining or inconsistent allegations are denied. Besins S.A. further denies that Plaintiffs' alleged injuries are the result of any wrongful conduct by Besins S.A. and that Plaintiffs are entitled to relief on any of the within claims or causes of action.

2. Besins S.A. admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in CMO 20 entered in the pending MDL relating to TRTs, and that individual plaintiffs are expected to utilize short-form complaints consistent with Exhibit A and CMO 20. Any remaining or inconsistent allegations are denied.

3. Besins S.A. admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in CMO 20 entered in the pending MDL relating to TRTs, and that individual plaintiffs are expected to utilize short form complaints consistent with Exhibit A and CMO 20. The Master Complaint, as well as any short-form complaints, being in writing, speak for themselves and any remaining or inconsistent allegations are denied. Besins S.A. further denies that Plaintiffs' alleged injuries are the result of any wrongful conduct by Besins S.A. and that Plaintiffs are entitled to relief on any of the within claims or causes of action.

**ANSWER TO ALLEGATIONS REGARDING
THE NATURE OF THIS ACTION**

4. Besins S.A. admits that Plaintiffs purport to seek compensation for personal injuries allegedly resulting from the use of various TRT products and that their claims, being in writing, speak for themselves. Besins S.A. denies that AndroGel, which has never been sold, marketed, or promoted for sale by Besins S.A. in the United States, was defective or that it caused the injuries alleged and further denies that Plaintiffs are in any way entitled to damages or other relief. Any remaining or inconsistent allegations are denied.

5. Besins S.A. admits that AndroGel is approved for use as indicated by its FDA-approved label. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

6. Besins S.A. admits that AndroGel, marketed in a 1% and 1.62% formulation, is one of several TRT products at issue in the pending MDL and that the Master Complaint, being in writing, speaks for itself. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

7. Besins S.A. denies engaging in any promotional activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United States related to hypogonadism. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

8. Besins S.A. admits that Androgen Deficiency in Adult Males (“ADAM”) refers to a set of questions regarding the signs and symptoms of hypogonadism and that the ADAM questionnaire, being in writing, speaks for itself. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

9. Denied.

10. Denied.

11. Denied.

**ANSWER TO ALLEGATIONS REGARDING
JURISDICTION AND VENUE**

12. The allegations in Paragraph 12 state legal conclusions to which no response is required. To the extent a response is required, upon reasonable investigation, Besins S.A. admits that diversity jurisdiction exists as to most of the claims brought by Plaintiffs in this MDL, generally, but reserves the right to challenge such jurisdiction in a particular case should further factual investigation reveal otherwise.

13. The allegations in Paragraph 13 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. admits that, upon information and belief, Plaintiffs are seeking in excess of seventy-five thousand dollars (\$75,000) in each individual case but denies that Plaintiffs are entitled to any recovery.

ANSWER TO ALLEGATIONS REGARDING PARTIES

Answer to Allegations Regarding Plaintiffs

14. Besins S.A. admits that Plaintiffs have filed a Master Complaint purportedly pursuant to and for the purposes set forth in CMO 20 entered in the pending MDL relating to TRTs. The Master Complaint, being in writing, speaks for itself. Besins S.A. denies that Plaintiffs' alleged injuries are the result of any wrongful conduct by Besins S.A. and further denies that Plaintiffs are entitled to relief on any of the within claims or causes of action.

15. Denied.

16. The allegations in Paragraph 16 state legal conclusions to which no response is required. To the extent a response is required, the averments of Paragraph 16 are denied.

Answer to Allegations Regarding Defendants

Answer to Allegations Regarding the AbbVie Defendants

17. In response to Paragraph 17 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

18. In response to Paragraph 18 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

19. In response to Paragraph 19 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

20. In response to Paragraph 20 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

21. In response to Paragraph 21 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

22. In response to Paragraph 22 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

23. In response to Paragraph 23 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

24. It is admitted that Besins Healthcare Inc. is a Delaware corporation with its principal place of business in Virginia, and is a wholly owned subsidiary of Besins S.A. Besins S.A. denies the remaining allegations in Paragraph 24, including subparts a-c.

25. It is admitted that Besins S.A. is a privately-held Belgian corporation, and that Besins S.A. has played a role in the manufacture of AndroGel from its offices and locations outside of the United States. It is denied that Besins S.A. is currently headquartered in Bangkok, Thailand, or that it has conducted any activity, manufacturing or otherwise, within the United States with respect to AndroGel. The remaining allegations in Paragraph 25 are denied. Besins S.A. states further that it is currently headquartered in Monaco.

26. It is admitted that Plaintiffs refer in their Complaint to Besins Healthcare Inc., and Besins S.A. collectively as “Besins.” It is denied that such characterization is reasonable, accurate, or appropriate.

27. It is admitted that Plaintiffs refer in their Complaint to AbbVie Inc., Abbott Laboratories, AbbVie Products LLC, Unimed Pharmaceuticals LLC, Besins Healthcare Inc., and Besins S.A. collectively as “AbbVie.” It is denied that such characterization is reasonable, accurate or appropriate. Besins S.A. denies that it may be “defined” as part of “AbbVie.” Besins S.A. does not file this Master Answer on behalf of any entity other than Besins S.A.

28. It is admitted that Plaintiffs’ claims against Besins S.A. purportedly relate to AndroGel 1% and 1.62%. Besins S.A. denies that such claims have merit and further denies that

Plaintiffs are entitled to relief on any of the within claims or causes of action. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

Answer to Allegations Regarding the Lilly Defendants

29. - 37. In response to Paragraphs 29-37 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations Regarding Endo, Auxilium, and GSK

38. - 43. In response to Paragraphs 38-43 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations Regarding the Pfizer Defendants

44. - 47. In response to Paragraphs 44-47 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations Regarding the Actavis Defendants

48. - 53. In response to Paragraphs 48-53 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

**ANSWER TO ALLEGATIONS OF FACTS
COMMON TO ALL CLAIMS**

Answer to Allegations Regarding the TRT Products

54. It is admitted that TRT products replace the androgen hormone testosterone, which is normally produced by men's bodies, there are various available methods of delivering this replacement hormone, and some, but not all, of these methods are identified in Paragraph 54. Any remaining or inconsistent allegations are denied.

55. It is admitted that AndroGel is delivered transdermally, it is applied to the skin in the form of a gel, and AndroGel is available in both a 1% and a 1.62% formulation. Besins S.A. further admits that it co-developed the pharmaceutical formulation for AndroGel, that it holds certain intellectual property rights related to AndroGel, and that it has, at relevant times, manufactured AndroGel at locations outside of the United States. Besins S.A. otherwise denies that Plaintiffs have accurately characterized the corporate relationships and transactions set forth in Paragraph 55, and further denies involvement in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

56. It is admitted that Besins S.A. co-developed the pharmaceutical formulation for AndroGel, and that it has, at relevant times, manufactured AndroGel at locations outside of the United States. Besins S.A. otherwise denies that it engaged in the activities set forth in Paragraph 56. By way of further response, Besins S.A. denies involvement in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

57. - 72. In response to Paragraphs 57-72 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

73. It is admitted that AndroGel delivers testosterone and that testosterone is the primary hormone responsible for normal male growth and development of male sex organs and secondary sex characteristics. It is further admitted that testosterone plays a role in many aspects of overall male health and well-being including but not limited to those identified in paragraph

73. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

74. It is admitted that the medical literature discusses the fact of some gradual, expected decline in testosterone levels in adult males over time. Any remaining or inconsistent allegations are denied.

75. It is admitted that some men suffer from medical conditions that impair their ability to make testosterone and that “primary hypogonadism” and “hypogonadotropic hypogonadism” refer to medical conditions which are associated with reduced or no production and levels of testosterone. Any remaining or inconsistent allegations are denied.

76. It is admitted that hypogonadism is a medical condition that is characterized by the nonproduction or underproduction of testosterone. It is further admitted that the medical community recognizes hypogonadism as an endocrine condition that may be appropriately treated, as well as the health benefits of normal testosterone levels. Any remaining or inconsistent allegations are denied.

77. It is admitted that AndroGel has been approved for use as a testosterone replacement therapy upon prescription of a learned intermediary and that the FDA approved label for AndroGel, being in writing, speaks for itself. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

Answer To Allegations Regarding Regulatory History and Approved Uses

78. - 85. In response to Paragraphs 78-85 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

86. The original approved AndroGel 1% product label, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

87. The original approved AndroGel 1.62% product label, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

88. The FDA approved AndroGel 1% and 1.62% product labels, being in writing, speak for themselves. Any remaining or inconsistent allegations are denied.

89. - 96. In response to Paragraphs 89-96 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

97. The FDA approved AndroGel 1% and 1.62% product labels, being in writing, speak for themselves. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

98. Denied.

Answer to Allegations Regarding Defendants' Marketing to Consumers and Physicians for Off-Label Use

99. The allegations in Paragraph 99 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that Paragraph 99 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

100. The allegations in Paragraph 100 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that Paragraph 100 fairly

characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

101. The allegations in Paragraph 101 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that Paragraph 101 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

102. The allegations in Paragraph 102 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that Paragraph 102 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

103. The allegations in Paragraph 103 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that Paragraph 103 fairly characterizes the federal regulation of prescription pharmaceuticals. Any remaining or inconsistent allegations are denied.

104. The allegations in Paragraph 104 state legal conclusions to which no response is required. To the extent a response is required, it is admitted that the FDA approved AndroGel for use as a testosterone replacement therapy upon prescription of a learned intermediary, and that the FDA-approved labels for AndroGel 1% and 1.62%, being in writing, speak for themselves. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

105. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

106. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

107. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

108. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

109. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

110. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of AbbVie's Off-Label Marketing

111. - 123. In response to Paragraphs 111-123 of the Complaint, Besins S.A. denies engaging in any promotional activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United States related to hypogonadism. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

124. Besins S.A. admits that AndroGel was mentioned on its website, which being in writing, speaks for itself. Besins S.A. denies any remaining or inconsistent allegations in Paragraph 124, including all subparts. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

125. - 138. In response to Paragraphs 125-138 of the Complaint, Besins S.A. denies engaging in any promotional activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United

States related to hypogonadism. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

Answer to Allegations of Lilly's Off-Label Marketing

139. - 203. In response to Paragraphs 139-203 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of Endo's Off-Label Marketing

204. - 253. In response to Paragraphs 204-253 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of Auxilium's and GSK's Off-Label Marketing

254. - 347. In response to Paragraphs 254-347 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of Pfizer's Off-Label Marketing

348. - 369. In response to Paragraphs 348-369 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer Regarding Allegations of Actavis's Off-Label Marketing

370. - 382. In response to Paragraphs 370-382 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

Answer Regarding Allegations of Defendants' Failure to Warn of the Risks and Dangers of TRT Products

383. - 404. In response to Paragraphs 383-404 of the Complaint, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United

States related to hypogonadism. Besins S.A, further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

405. In response to Paragraph 405 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

406. In response to Paragraph 406 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

407. In response to Paragraph 407 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

408. In response to Paragraph 408 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

409. In response to Paragraph 409 of the Complaint, as the allegations are not directed to Besins S.A., Besins S.A. makes no response.

410. Admitted.

411. Denied that Paragraph 411 accurately or completely describes the conclusions of the “Vigen Paper” or that such study reached any reliable or accurate conclusions.

412. Admitted.

413. Denied.

414. Denied.

415. It is admitted that on or about June 19, 2014, the FDA issued an announcement regarding the modification of certain approved warning language. The FDA’s announcement, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

416.- 425. In response to Paragraphs 416-425 of the Complaint, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United States related to hypogonadism. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

426. It is admitted that on March 3, 2015 the FDA issued an FDA Drug Safety Communication, which being in writing speaks for itself. Besins S.A. denies any remaining or inconsistent allegations. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of Defendants' Fraud on the FDA

427. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

428. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

429. The allegations in Paragraph 429 state legal conclusions to which no response is required. To the extent a response is required, it is denied that Plaintiffs have completely or accurately set forth the entirety of 21 U.S.C. § 331 or fairly conveyed its meaning. Any remaining or inconsistent allegations are denied.

430. The allegations in Paragraph 430 state legal conclusions to which no response is required. To the extent a response is required, it is denied that Plaintiffs have completely or

accurately set forth the entirety of 21 U.S.C. § 352 or fairly conveyed its meaning. Any remaining or inconsistent allegations are denied.

431. The allegations in Paragraph 431 state legal conclusions to which no response is required. To the extent a response is required, it is admitted only that Plaintiffs have accurately transcribed 21 U.S.C. § 321(n). Any remaining or inconsistent allegations are denied.

432.- 441. In response to Paragraphs 432-441 of the Complaint, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT, and further denies any involvement in disease state awareness activities in the United States related to hypogonadism. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

442. It is admitted that the quoted language is part of a letter to the editor that appeared in the New England Journal of Medicine in 2004 attributed to Dr. Daniel Shames, Food and Drug Administration. Besins S.A. denies that this letter represents the view of FDA and otherwise denies any remaining or inconsistent allegations.

443. Besins S.A. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 443 and they are, therefore, denied.

444. Besins S.A. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 444 and they are, therefore, denied.

445. Denied. By way of further response, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels

and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

446.- 451. In response to Paragraphs 446-451 of the Complaint, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

452. Besins S.A. admits that Lisa M. Schwartz, M.D., M.S. and Steven Woloshin, M.D., M.S. are identified as authoring an “Invited Commentary” on or around August 26, 2013, titled *Low T as a Template: How to Sell Disease*, in *JAMA* which, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

453.- 459. In response to Paragraphs 453-459 of the Complaint, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

460. It is admitted that a Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee (“Ad. Comm.”) was convened on September 17, 2014 and that the agenda, being in writing, speaks for itself. Any remaining or inconsistent allegations are denied.

461. It is admitted that the Ad. Comm. published Summary Minutes on October 5, 2014. The Summary Minutes, being in writing, speak for themselves and any remaining or inconsistent allegations are denied.

462. Denied. By way of further response, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

Answer to Allegations of Fraudulent Concealment and Discovery Rule

463. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

464. The allegations in Paragraph 464 state legal conclusions to which no response is required. To the extent a response is required, denied.

465. The allegations in Paragraph 465 state legal conclusions to which no response is required. To the extent a response is required, denied.

466. The allegations in Paragraph 466 state legal conclusions to which no response is required. To the extent a response is required, denied.

ANSWER TO CLAIMS FOR RELIEF

ANSWER TO FIRST CLAIM FOR RELIEF

Strict Liability – Design Defect

467. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

468. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

469. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

470. The allegations in Paragraph 470 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

471. The allegations in Paragraph 471 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

472. The allegations in Paragraph 472 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

473. Besins S.A. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 473 and they are, therefore, denied.

474. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

475. The allegations in Paragraph 475 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

476. The allegations in Paragraph 476 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO SECOND CLAIM FOR RELIEF

Strict Liability – Failure to Warn

477.- 486. In response to Paragraphs 477-486 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Second Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO THIRD CLAIM FOR RELIEF

Negligence

487. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

488. The allegations in Paragraph 488 state legal conclusions to which no response is required. To the extent a response is required, it is denied that Besins S.A. engaged in all of the activities set forth in Paragraph 488. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

489. The allegations in Paragraph 489 state legal conclusions to which no response is required. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

490. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

491. The allegations in Paragraph 491 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that it has ever engaged in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

492. The allegations in Paragraph 492 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

493. The allegations in Paragraph 493 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

494. The allegations in Paragraph 494 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

495. The allegations in Paragraph 495 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

496. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

497. The allegations in Paragraph 497 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

498. The allegations in Paragraph 498 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

499. The allegations in Paragraph 499 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

500. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

501. The allegations in Paragraph 501 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further

denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

502. The allegations in Paragraph 502 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that it has ever engaged in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

503. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

504. The allegations in Paragraph 504 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

505. The allegations in Paragraph 505 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies engaging in any promotional or sales activities in the United States related to AndroGel or any other TRT. Besins S.A. further denied that it played any role in developing the FDA-approved product labels and medication guides for AndroGel. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

506. The allegations in Paragraph 506 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

ANSWER TO FOURTH CLAIM FOR RELIEF

Negligent Misrepresentation

507.- 518. In response to Paragraphs 507-518 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Fourth Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO FIFTH CLAIM FOR RELIEF

Breach of Implied Warranty of Merchantability

519.- 528. In response to Paragraphs 519-528 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Fifth Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO SIXTH CLAIM FOR RELIEF

Breach of Express Warranty

529.- 539. In response to Paragraphs 529-539 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Sixth Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO SEVENTH CLAIM FOR RELIEF

Fraud

540.- 562. In response to Paragraphs 540-562 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Seventh Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO EIGHTH CLAIM FOR RELIEF

Redhibition

563. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

564. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

565. The allegations in Paragraph 565 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that it has ever engaged in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

566. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

567. The allegations in Paragraph 567 state legal conclusions to which no response is required. To the extent a response is required, Besins S.A. denies that it has ever engaged in any promotional or sales activities in the United States related to AndroGel or any other TRT. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response. Any remaining or inconsistent allegations are denied.

568. The allegations in Paragraph 568 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO NINTH CLAIM FOR RELIEF

Consumer Protection

569.- 624. In response to Paragraphs 569-624 of the Complaint, Besins S.A. notes that the Court on September 30, 2015 dismissed Plaintiffs' Ninth Claim for Relief as to Besins S.A. and thus no response is required.

ANSWER TO TENTH CLAIM FOR RELIEF

Unjust Enrichment

625. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

626. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

627. Besins S.A. lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 627 and they are, therefore, denied.

628. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

629. The allegations in Paragraph 629 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO ELEVENTH CLAIM FOR RELIEF

Wrongful Death

630. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

631. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

632. The allegations in Paragraph 632 state legal conclusions to which no response is required. To the extent the averments of Paragraph 632 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

633. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

634. The allegations in Paragraph 634 state legal conclusions to which no response is required. To the extent the averments of Paragraph 634 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

635. The allegations in Paragraph 635 state legal conclusions to which no response is required. To the extent the averments of Paragraph 635 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

636. The allegations in Paragraph 636 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO TWELFTH CLAIM FOR RELIEF

Survival Action

637. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

638. The allegations in Paragraph 638 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

639. The allegations in Paragraph 639 state legal conclusions to which no response is required. To the extent the averments of Paragraph 639 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

640. The allegations in Paragraph 640 state legal conclusions to which no response is required. To the extent the averments of Paragraph 640 can be construed to suggest that Plaintiffs' claims are valid, those averments are denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

641. The allegations in Paragraph 641 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO THIRTEENTH CLAIM FOR RELIEF

Loss of Consortium

642. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

643. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

644. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

645. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

646. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

647. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

648. The allegations in Paragraph 648 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

649. The allegations in Paragraph 649 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

ANSWER TO FOURTEENTH CLAIM FOR RELIEF

Punitive Damages

650. Besins S.A. incorporates by reference the preceding paragraphs of this Master Answer as if fully set forth herein.

651. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

652. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

653. Denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

654. The allegations in Paragraph 654 state legal conclusions to which no response is required. To the extent a response is required, denied. As to any allegations that are not directed to Besins S.A., Besins S.A. makes no response.

RESPONSE TO “PRAYER FOR RELIEF”

Responding to the unnumbered WHEREFORE paragraph following Paragraph 654 of the Complaint, including each subpart, Besins S.A. denies that its conduct or AndroGel caused or contributed to Plaintiffs’ injuries and denies that it is liable to Plaintiffs for damages or any other relief sought in the Complaint.

AFFIRMATIVE DEFENSES

Besins S.A. asserts the following affirmative defenses, which shall apply to this Master Complaint as well as any individual complaint that is or should, at any time, become part of this MDL. By asserting these affirmative defenses, Besins S.A. does not allege or admit that it has the burden of proof or the burden of persuasion with respect to any of these matters.

FIRST DEFENSE

655. Plaintiffs’ Master Complaint fails to state a claim upon which relief may be granted.

SECOND DEFENSE

656. To the extent one or more of the claimants covered by this Master Complaint filed and/or had their action removed to any improper or inconvenient forum, such complaint

should be dismissed and/or transferred for lack of venue and/or on the grounds of *forum non conveniens*.

THIRD DEFENSE

657. Plaintiffs' claims may be barred by the doctrine(s) contained in Restatement (Second) of Torts § 402A, and comments thereto, including but not limited to comments j and k, and/or Restatement (Third) of Torts: Products Liability §§ 2, 4 and 6 and comments thereto.

FOURTH DEFENSE

658. Plaintiffs' claims may be barred because the risks alleged to be associated with the use of AndroGel were outweighed by the medication's utility.

FIFTH DEFENSE

659. Plaintiffs' claims may be barred, in whole or in part, by misuse or unintended use of AndroGel.

SIXTH DEFENSE

660. Plaintiffs' claims may be barred, in whole or in part, by the learned intermediary or informed intermediary doctrine.

SEVENTH DEFENSE

661. Plaintiffs' claims may be barred because Plaintiffs' injuries, if any, were caused, in whole or in part, by the intervening or superseding conduct of Plaintiffs, independent third parties, or events that were extraordinary under the circumstances, not foreseeable in the normal course, or independent of or far removed from Besins S.A.'s conduct or control.

EIGHTH DEFENSE

662. Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs provided learned or informed consent to the use of AndroGel.

NINTH DEFENSE

663. Plaintiffs' claims may be barred, in whole or in part, by the doctrines of comparative fault or contributory negligence.

TENTH DEFENSE

664. Plaintiffs' claims may be barred, in whole or in part, by the negligent and/or otherwise wrongful conduct of others, constituting an intervening or superseding cause of the alleged harm

ELEVENTH DEFENSE

665. Plaintiffs' fraud-based claims may be barred for failure to plead them with the requisite particularity or specificity.

TWELFTH DEFENSE

666. Plaintiffs' fraud-based claims may be barred, in whole or in part, because Plaintiffs did not rely to their detriment upon any statement by Besins S.A. in determining to use AndroGel.

THIRTEENTH DEFENSE

667. Plaintiffs' claims may be barred, in whole or in part, by applicable statutes of limitations and/or repose.

FOURTEENTH DEFENSE

668. To the extent any Complaint asserts claims for breach of express or implied warranty, Plaintiffs lack the requisite privity with Besins S.A. to sustain such claims.

FIFTEENTH DEFENSE

669. To the extent any Complaint asserts claims for breach of express or implied warranty, such claims are barred because Plaintiffs did not reasonably rely on any alleged

express or implied warranty, and because Plaintiffs did not give Besins S.A. adequate notice of any alleged breach of warranty, express or implied.

SIXTEENTH DEFENSE

670. Plaintiffs' claims may be barred, in whole or in part, by the doctrines of waiver, laches, estoppel, release, or statutory and regulatory compliance.

SEVENTEENTH DEFENSE

671. Plaintiffs' damages, if any, may be barred, limited, or offset in the amount of any reimbursement received by Plaintiffs as a result of any insurance or other health benefits plan, or any amounts paid by any insurance or other health benefits plan.

EIGHTEENTH DEFENSE

672. Plaintiffs' claims may be barred, in whole or in part, by the doctrine of assumption of risk.

NINETEENTH DEFENSE

673. Plaintiffs' claims are barred because AndroGel was designed, manufactured and marketed in accordance with the state of the art and when AndroGel left the control of Besins S.A. no practical and technically feasible alternative formulation was available that would have prevented the harm for which Plaintiffs seek to recover without substantially impairing the safety, efficacy, or usefulness of the products for their intended use.

TWENTIETH DEFENSE

674. Plaintiffs' damages, if any, may be limited, in whole or in part, by Plaintiffs' failure to mitigate.

TWENTY-FIRST DEFENSE

675. Plaintiffs' claims are barred, in whole or in part, because AndroGel is comprehensively regulated by the United States Food and Drug Administration ("FDA") pursuant to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq., and regulations promulgated thereunder, and Plaintiffs' claims conflict with the FDCA, with the regulations promulgated by the FDA to implement the FDCA, with the purposes and objectives of the FDCA and the FDA's implementing regulations, and with determinations by the FDA specifying the language that should be used in the labeling accompanying AndroGel. Accordingly, Plaintiffs' claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

TWENTY-SECOND DEFENSE

676. Plaintiffs' claims may be barred, in whole or in part, under the doctrine of primary jurisdiction, in that the pertinent conduct of Besins S.A. and its activities with respect to AndroGel, have been and are conducted under the supervision of the FDA.

TWENTY-THIRD DEFENSE

677. To the extent that Plaintiffs seek punitive, exemplary, or aggravated damages, any such damages are barred because the product at issue, and its labeling, were subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

TWENTY-FOURTH DEFENSE

678. Plaintiffs' claims are barred, in whole or in part, by the deference that common law gives to discretionary actions by the FDA under the FDCA.

TWENTY-FIFTH DEFENSE

679. Besins S.A. is entitled to, and claims the benefit of, all defenses and presumptions set forth in or arising from any applicable law or rule of law or governing statute of any state, including but not limited to any relevant product liability acts and/or consumer fraud and/or unfair competition acts, that would bar or otherwise limit any of the claims asserted by Plaintiffs.

TWENTY-SIXTH DEFENSE

680. To the extent Plaintiffs seek recovery of punitive or exemplary damages against Besins S.A., any such damages are barred and/or limited by applicable laws and/or standards of proof.

TWENTY-SEVENTH DEFENSE

681. To the extent Plaintiffs seek recovery of punitive, exemplary or aggravated damages against Besins S.A., any such damages claims are in violation of and are barred by the Constitution of the United States and any relevant comparable state constitutional provisions, including but not limited to, the Due-Process and Equal Protection Clauses contained in the Fifth and Fourteenth Amendments; the Excessive Fines Clause of the Eighth Amendment; and the Tenth Amendment.

TWENTY-EIGHTH DEFENSE

682. To the extent that Plaintiffs seek punitive, exemplary, or aggravated damages, Besins S.A. specifically incorporates by reference any and all standards or limitations regarding the termination and enforceability of punitive or aggravated damages which arose in the decision of *BMW of North America v. Gore*, 517 U.S. 559 (1996) and cases subsequent to *BMW*, including *Philip Morris USA v. Williams*, 549 U.S. 346 (2007).

TWENTY-NINTH DEFENSE

683. Plaintiffs' claims may be barred because of Plaintiffs' failure to join necessary and indispensable parties.

THIRTIETH DEFENSE

684. To the extent Plaintiffs' claims related to Besins S.A.'s advertising, public statements, lobbying, or other activities protected by the First Amendment to the Constitution of the United States or by the constitutions of any applicable state, such claims are barred.

THIRTY-FIRST DEFENSE

685. To the extent Plaintiffs assert claims that depend solely on violations of federal law, including claims of a "fraud on the FDA" with respect to Besins S.A.'s disclosure of information related to the safety of AndroGel, such claims are barred and should be dismissed. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

THIRTY-SECOND DEFENSE

686. To the extent applicable, Besins S.A. asserts and preserves all claims for indemnification and/or contribution from any person and/or entity whose negligence or other fault contributed to Plaintiffs' alleged injuries and damages.

THIRTY-THIRD DEFENSE

687. Should Besins S.A. be held liable to Plaintiffs, which is specifically denied, Besins S.A. would be entitled to a set-off for all sums of money received or available from or on behalf of any tortfeasors for the same injuries alleged in Plaintiffs' Complaint.

THIRTY-FOURTH DEFENSE

688. Plaintiffs' claims may be barred because Besins S.A. at all times conformed to the requirements of the FDA, as well as all state and federal statutes, regulations, and industry standards based upon the state of knowledge existing at the relevant time(s).

THIRTY-FIFTH DEFENSE

689. Plaintiffs' claims may be barred because Plaintiffs have failed to comply with conditions precedent necessary to bring this action and/or each particular cause of action asserted by Plaintiffs.

THIRTY-SIXTH DEFENSE

690. Besins S.A. incorporates all available state-law defenses including all defenses applicable under state product liability, consumer protection, unfair competition and/or consumer fraud statutes, whether or not specifically enumerated in the Master Complaint.

THIRTY-SEVENTH DEFENSE

691. Besins S.A. hereby preserves any and all defenses of lack of personal jurisdiction which may be determined to apply in the context of one or more individual complaints.

THIRTY-EIGHTH DEFENSE

692. Plaintiffs' claims may be barred, in whole or in part, because Plaintiffs lack standing to bring such claims.

DEMAND FOR JURY TRIAL

Besins S.A. demands a trial by jury.

WHEREFORE, Besins S.A. requests that Plaintiffs' Master Complaint be dismissed in its entirety with prejudice, that judgment be entered in favor of Besins S.A., that Besins S.A. be awarded costs and, to the extent provided by law, attorneys' fees, and any such other relief as the Court may deem proper.

Respectfully submitted,

Dated: October 31, 2016

/s/ David M. Bernick

David M. Bernick

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Attorneys for Besins Healthcare, S.A.

CERTIFICATE OF SERVICE

I, Christopher Boisvert, hereby certify that on October 31, 2016, the foregoing document was filed via the Court's CM/ECF system, which will automatically serve and send email notifications of such filing to all registered attorneys of record.

/s/ Christopher Boisvert